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1 RECORD OF ORAL HEARING
2
3 UNITED STATES PATENT AND TRADEMARK OFFICE
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5
6 BEFORE THE BOARD OF PATENT APPEALS
7 AND INTERFERENCES
8

9
10 *Ex parte* RICHARD LAZZARA, THOMAS S. HEYLMUN, and
11 KEITH D. BEATY
12

13
14 Appeal No. 2010-001766
15 Application No. 09/237,605
16 Technology Center 3700
17

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19 Oral Hearing Held: January 19, 2012
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21
22 Before JENNIFER D. BAHR, LINDA E. HORNER and
23 EDWARD A. BROWN, *Administrative Patent Judges*.
24

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36 The above-entitled matter came on for hearing on Thursday, January 19,
37 2012, commencing at 1:35 p.m., at the U.S. Patent and Trademark Office,
38 600 Dulany Street, Alexandria, Virginia, before Paula Lowery, Notary
39 Public.
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P R O C E E D I N G S

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MS. BAIO: I have the next case, too.

JUDGE BAHR: You can begin.

MS. BAIO: This is serial number 09/237,605. These claims are directed to titanium dental implants and methods of forming where the implants have acid-etched surfaces that are formed during a second process step.

For example, after a native oxide has been removed and/or as specifically called out in Claim 51 using a second acid solution the acid-etched surfaces extend to the lowermost end of the implant and they have an array of irregularities having peak to valley heights again of not greater than about 10 microns, where the irregularities include cone shaped elements.

JUDGE HORNER: Do these claims cover implants made of commercially pure or titanium alloy?

MS. BAIO: I believe so.

Oh, no, these are just titanium.

JUDGE HORNER: You say "just titanium." What does that mean? Just commercially pure titanium?

MS. BAIO: Well, the preamble says "titanium metal", so I believe they're limited to just simply titanium.

JUDGE HORNER: That "titanium metal" is intended to mean commercially pure titanium?

MS. BAIO: I believe so, since our other claims specifically say "titanium" or "titanium alloy."

1 JUDGE HORNER: What about 63? It says a “titanium dental implant.”

2 Does that mean titanium as opposed to titanium alloy?

3 MS. BAIO: I believe it does. Like I said, I see the other claims say

4 “titanium” or “titanium alloy.”

5 JUDGE BAHR: Is there anything in the specification that might help us
6 determine for certain?

7 MS. BAIO: Let me look. I think that's not really relied upon in our

8 arguments, but I do see why it could be important.

9 In the description we say such implants are normally machined from
10 titanium or titanium alloy. The process has two steps, the first being
11 removal of the native oxide from titanium --

12 JUDGE HORNER: I notice your original Claim 5 further limited the dental
13 implant of Claim 1 where the implant is titanium or a titanium alloy. So you
14 seem to be distinguishing between titanium --

15 MS. BAIO: Maybe I was wrong, and it is titanium and titanium alloy.

16 JUDGE HORNER: I guess I'm reading it as this is a distinction in the claim
17 between when you use the word titanium meaning something other than an
18 alloy and then you took care to add titanium alloy in that particular original
19 claim to distinguish the two.

20 So that seems to support your position perhaps that titanium in the claims
21 just refers to commercially pure titanium.

22 MS. BAIO: I apologize for not knowing the answer offhand.

23 I'm looking at the Porter declaration which was submitted to show
24 commercial success. He kind of goes through the claim elements but simply
25 says titanium as well. The threaded implant is made of titanium.

1 JUDGE HORNER: It seems like in the amendment to the specification
2 where you incorporated the Beaty disclosure, the examples were all to
3 commercially pure titanium for what it's worth.

4 JUDGE BROWN: I don't believe "titanium metal" shows up anywhere in
5 the specification.

6 JUDGE HORNER: We did not see the wording "titanium metal" in the
7 specification, only reference to titanium or commercially pure titanium.

8 MS. BAIO: I'm just not a hundred percent positive without having a chance
9 to look into the declarations that were submitted and trying to recreate the
10 surface.

11 Let me look in one more place.

12 I think it is commercially pure titanium. I see in the Gubbi declaration the
13 first experiment that he did was recreating the Osseotite surface. He used
14 commercially pure titanium. That might be the answer.

15 Again, I apologize for not having that off hand.

16 So all the claims have been rejected under Section 103 in view of Haruyuki
17 or Wennerberg -- over Haruyuki or Wennerberg in view of Niznick.

18 So we submit that the applied references and the combinations thereof do
19 not result in the inventions claimed.

20 The Examiner is relying on Haruyuki and Wennerberg to show basically all
21 of the elements of the claims except for different regions of roughness and
22 locations thereof for which he relies on Niznick.

23 Haruyuki and Wennerberg, however, do not disclose all the elements that the
24 Examiner relies on them for. For example, in Haruyuki the surface is simply
25 not the same as the Appellant's surface.

1 There is no disclosure in Haruyuki of a second treatment that roughens the
2 surface. Instead, what Haruyuki does is it applies hydrofluoric acid in the
3 first step to do the roughening, and then there's a second process step using
4 hydrochloric acid and hydrogen peroxide to smooth that resulting roughened
5 surface.

6 There's also a structural difference between the claimed surface and
7 Haruyuki's surface, perhaps due to the second smoothing step. This
8 distinction is made clear by Dr. Gubbi's experiments which, like I said, are
9 detailed in his declaration.

10 JUDGE HORNER: So are you reading the claim to require the roughening
11 to be simply a result of the second -- the acid etching step and not the
12 combination of the native oxide layer removal step plus the acid-etching
13 step?

14 MS. BAIO: No, I think it is a combination of. I think removing the native
15 oxide does roughen the surface, but then we further roughen the surface.

16 JUDGE HORNER: Okay.

17 MS. BAIO: Using the second acid.

18 JUDGE HORNER: But if Haruyuki's method is roughening the surface with
19 the first step and smoothing out some peaks with the second step, don't you
20 still result in a roughened surface?

21 MS. BAIO: You do, but it's not resulting from a second process step like in
22 our claims.

23 Furthermore, I think the surfaces of Haruyuki actually are different than our
24 claimed surfaces.

1 So if you look at the photographs submitted in the Gubbi declaration and
2 also in -- I think it's Exhibit 9 of our Appeal Brief -- where we --

3 JUDGE HORNER: So Exhibit B shows the results of Dr. Gubbi's attempt to
4 recreate the examples from Haruyuki?

5 MS. BAIO: Right, which don't match up with Haruyuki's photographs,
6 which is another defect we see with Haruyuki. The fact that you can't
7 reproduce his surfaces seems to call into question his disclosure.

8 JUDGE HORNER: Can you explain to me comparing the 3-D surface map
9 in Exhibit A, which is your Osseotite surface, and comparing that with, for
10 example, Example 3, the 3-D surface map shown in Exhibit B -- what the
11 differences are in terms of the cone-shaped structures and also how we can
12 tell from these 3-D maps what the peak-to-valley heights are?

13 MS. BAIO: It looks to me like the roughening in Haruyuki is smoother
14 really compared to our surface.

15 JUDGE HORNER: It appears to have peaks from this 3-D surface map.

16 MS. BAIO: It does have some peaks, but I think the entire surface is just
17 generally smoother. Which, obviously, I think is a result of the second
18 process step to smooth the surface.

19 JUDGE HORNER: How can you tell it's smoother?

20 MS. BAIO: Well, if you look at Exhibit A of Gubbi, there's more of these
21 peaks. They look more distinct. I mean, even the
22 color -- it seems to be more -- I'm not sure if you have the color version in
23 front of you.

24 JUDGE HORNER: We do.

1 MS. BAIO: Okay, there seems to be more variation in the brown, which
2 would depict the pits or valleys, I should say, in the claims.

3 JUDGE HORNER: I see.

4 MS. BAIO: Whereas, Haruyuki -- I don't know how else to explain. It just
5 looks smoother.

6 JUDGE HORNER: The Examiner pointed to these 3-D surface maps of Dr.
7 Gubbi's reproduction of Haruyuki's examples as evidence that it forms cone-
8 shaped elements, which it appears to have peaks that look like they're in the
9 shape of cones, correct?

10 MS. BAIO: Right. But that's the only thing the Examiner is citing for cone-
11 shaped elements is Dr. Gubbi's reproduction of the surfaces.

12 JUDGE HORNER: But Dr. Gubbi has attested that he followed exactly the
13 example given in Haruyuki's spec and it results in cone-shaped elements,
14 and that's the Examiner's position. So doesn't this support that view that
15 these are cone-shaped?

16 MS. BAIO: But the photographs in Haruyuki itself don't show cone-shaped
17 elements. So the surface reproduced by Gubbi seems to be a different one
18 than Haruyuki has shown and described.

19 JUDGE HORNER: But we don't have a 3-D surface map in Haruyuki,
20 right?

21 MS. BAIO: If you look at the 2-D photos, they're different. What Dr.
22 Gubbi has recreated is different from what Haruyuki has shown in its
23 examples.

24 I guess you can just infer to the 3-D surfaces that also appear to be different.

1 JUDGE HORNER: We have no way to tell if these are cone-shaped or not
2 from the 2-D image, do we?

3 MS. BAIO: No, other than the fact that because the surfaces he describes
4 are different than what actually results. To me it's almost like a big question
5 mark of what Haruyuki is actually disclosing, especially with regard to the
6 cone-shaped elements which it doesn't discuss at all.

7 JUDGE HORNER: What about the peak to valley height not greater than 10
8 microns?

9 MS. BAIO: I don't think Dr. Gubbi measured that. I'm not sure why.

10 JUDGE HORNER: So this evidence doesn't tell us anything one way or the
11 other on the peaks and valley?

12 MS. BAIO: About peak and valley heights, I don't think so.

13 JUDGE HORNER: Okay.

14 JUDGE BROWN: Does your claim require that each one of those
15 irregularities have that peak to valley height? Some of them? How do you
16 interpret that?

17 MS. BAIO: The claim says having peak and valley heights -- it just says the
18 roughened region includes an array of irregularities having peak-to-valley
19 heights not greater than 10 microns.

20 JUDGE BROWN: So it could include peaks that don't have that?

21 MS. BAIO: I think it could. I just think it's probably a majority would be
22 less than 10 microns -- the vast majority.

23 JUDGE BROWN: So you could possibly have some average above 10 for
24 the height?

1 MS. BAIO: An average? I don't think you'd have an average above 10. I
2 don't think the spec could be interpreted that way.

3 We pretty much set forth the less than 10 micron limitation, although that's
4 not explicitly stated.

5 JUDGE HORNER: So Haruyuki discloses a pore depth, pit, or whatever
6 you call the irregularities of .5 to 5 microns average. Average pore depth of
7 .5 to 5 microns.

8 MS. BAIO: I think it's .05.

9 JUDGE HORNER: Maybe it was --

10 MS. BAIO: No, you're right. It's .5 to 5.

11 JUDGE HORNER: That's an average which means some of the pores might
12 be deeper than 5 microns, let's say; but on average, the average is .5 to 5.

13 MS. BAIO: Right. I think the problem with that is wanting to combine
14 Haruyuki with Niznick, which discloses a need for a much rougher surface.
15 On the order of over 25 microns.

16 So our argument there is one skilled in the art would not combine these two
17 references because they spell out this kind of important requirement of what
18 they want their surface roughness to be.

19 For example, Haruyuki teaches that it applies its second acid treatment in
20 order to smooth the roughened surface. Saying if the surface roughness is
21 greater than 5 microns, it could cause tissue irritation which might lead to
22 cancer.

23 So I think that's clearly a teaching away from making the surface any greater
24 than 5 microns by stressing the importance of the less than 5 micron
25 limitation really in Haruyuki.

1 Whereas Niznick teaches that the surface should be exceedingly rough, on
2 the order of greater than 25 microns, which is at least 5 times the surface
3 roughness of Haruyuki.

4 Another distinction between the two references that teaches away from the
5 combination is how the roughness is achieved. Haruyuki etches the titanium
6 metal, and Niznick's surface texture is created from hydroxy appetite
7 coating.

8 Haruyuki itself actually teaches away from such a material-adding procedure
9 by saying this process might introduce biotissue contamination and the
10 processes are more complex and expensive.

11 JUDGE HORNER: I think though that Niznick discloses at least for the
12 self-tapping threads at the bottom of the dental implant that those having an
13 average peak to valley distance of no greater than 20 microns can be formed
14 by acid etching with a concentration of hydrofluoric acid or other suitable
15 acids as one example.

16 Those are uncoated, so they don't have the same coating as the middle
17 region.

18 MS. BAIO: But the middle region is still disclosed to be a surface
19 roughness greater than 25 microns. So nowhere does Niznick disclose using
20 a smaller surface roughness.

21 JUDGE HORNER: The Examiner is not relying on Niznick to teach how to
22 form a surface roughness on an implant, right? Haruyuki teaches that.
23 Haruyuki does mention implants for dentistry, so he's really relying on
24 Niznick to say here's what a conventional dental implant looks like, and
25 here's where you would roughen it using Haruyuki's method.

1 MS. BAIO: It's true he's not relying on Niznick to show the level of
2 roughness, but our argument is that because of these important distinctions
3 between Haruyuki and Niznick, one skilled in the art wouldn't have ever
4 looked -- one skilled in the art reading Haruyuki would never have even
5 looked at Niznick to glean anything from it.
6 Along those same lines, another issue is Niznick teaches a smoother self-
7 tapping portion. So its roughness, like you mentioned, is different in that the
8 threaded portion -- I guess immediately under the neck versus the self-
9 tapping portions.
10 So it doesn't disclose a uniform roughened surface, which is in Claim 51. It
11 also doesn't disclose the acid-etched surface extending to the lowermost end
12 of the implant within the self-tapping region, because it stresses that the self-
13 tapping region should not be roughened -- or minimally roughened -- in
14 order to maintain the sharpness of those edges.
15 It's the self-tapping region that's really used to cut through the bone and get
16 the implant in.
17 So there is another deficiency with respect to Niznick.
18 Now we haven't talked about Wennerberg at all. That one is a little bit
19 easier. In Wennerberg there's no disclosure whatsoever of acid etching. The
20 implants that are specifically referred to in Wennerberg are the 3-I MiniPlant
21 implants, which is owned by 3-I who's also the assignee of this application;
22 and the Nobelpharma implants, which both have machined surfaces.
23 So Wennerberg specifically states that the differences in the surface
24 topography in those implants are attained by varying the sharpness of the
25 cutting tools. So there's no acid etching process applied to those implants.

1 Interestingly, Niznick also discusses machined surfaces and specifically
2 mentions the Nobelpharma implant innovation implants.
3 Therefore, we submit that it's not obvious to combine Wennerberg with
4 Niznick also because there's just no motivation why one skilled in the art
5 would apply an exceedingly rough surface of Niznick with the machine to
6 smooth surfaces of Wennerberg.

7 We also submitted -- I wanted to quickly highlight the Porter declaration,
8 which discusses the commercial success of the claimed Osseotite surface.

9 In his declaration he tracks the claims of the present invention with the
10 Osseotite process. So he clearly establishes a nexus between the present
11 application and Osseotite.

12 He also talks about, like I said, the commercial success of Osseotite. He
13 mentions the rapid sales increase of Osseotite relative to other implants.

14 He talks about how Osseotite has been and still is -- despite the fact that this
15 application was filed in 1999 -- considered one of the gold standards of
16 dental implants.

17 So there is lots of other companies that compare their surfaces to Osseotite
18 trying to suggest that their surfaces are just as good or better.

19 He also discusses the clinically proven enhanced osseointegration due to the
20 Osseotite surface.

21 That's the bulk of our arguments with respect to the independent claims. I
22 thought I'd highlight a couple of the dependent claims.

23 Claims 61, 67, and 72 which specifically mention the second acid solution is
24 a mixture of sulfuric and hydrochloric acid. That's not disclosed on the
25 applied references.

1 Haruyuki, for example, only discloses hydrochloric acid and hydrogen
2 peroxide which, obviously, produced a different result.

3 JUDGE BAHR: Any other questions?

4 JUDGE HORNER: No, I don't think so. You've given us a lot to think
5 about.

6 MS. BAIO: Thank you very much.

7 (Whereupon, the proceedings at 1:57 p.m. were concluded.)

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